



Edition: BP 2025 (Ph. Eur. 11.6 update)

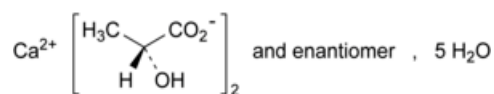
Calcium Lactate Pentahydrate



[General Notices](#)

Calcium Lactate

(*Ph. Eur. monograph 0468*)



$\text{C}_6\text{H}_{10}\text{CaO}_6 \cdot 5\text{H}_2\text{O}$ 308.3

Action and use

Used in treatment of calcium deficiency.

Preparations

[Calcium and Ergocalciferol Tablets](#)

[Calcium Lactate Tablets](#)

[Calcium and Ergocalciferol Chewable Tablets](#)

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DEFINITION

Calcium bis[(2 Ξ)-2-hydroxypropanoate] or mixture of calcium (2*R*)-, (2*S*)- and (2*RS*)-2-hydroxypropanoates pentahydrates.

Content

98.0 per cent to 102.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline or granular powder, slightly efflorescent.

Solubility

Soluble in water, freely soluble in boiling water, very slightly soluble in ethanol (96 per cent).

IDENTIFICATION

- A. Loss on drying (see Tests).
- B. It gives the reaction of lactates ([2.3.1](#)).
- C. It gives reaction (b) of calcium ([2.3.1](#)).

TESTS

Solution S

Dissolve 7.1 g (equivalent to 5.0 g of the dried substance) with heating in [carbon dioxide-free water R](#) prepared from [distilled water R](#), allow to cool and dilute to 100 mL with the same solvent.

Appearance of solution

Solution S is not more opalescent than reference suspension II ([2.2.1](#)) and not more intensely coloured than reference solution BY₆ ([2.2.2, Method II](#)).

Acidity or alkalinity

To 10 mL of solution S add 0.1 mL of [phenolphthalein solution R](#) and 0.5 mL of [0.01 M hydrochloric acid](#). The solution is colourless. Not more than 2.0 mL of [0.01 M sodium hydroxide](#) is required to change the colour of the indicator to pink.

Chlorides ([2.4.4](#))

Maximum 200 ppm.

Dilute 5 mL of solution S to 15 mL with [water R](#).

Sulfates ([2.4.13](#))

Maximum 400 ppm.

Dilute 7.5 mL of solution S to 15 mL with [distilled water R](#).

Iron ([2.4.9](#))

Maximum 50 ppm.

Dilute 4 mL of solution S to 10 mL with [water R](#).

Magnesium and alkali salts

Maximum 1 per cent.

To 20 mL of solution S add 20 mL of [water R](#), 2 g of [ammonium chloride R](#) and 2 mL of [dilute ammonia R1](#). Heat to boiling and rapidly add 40 mL of hot [ammonium oxalate solution R](#). Allow to stand for 4 h, dilute to 100.0 mL with [water R](#) and filter. To 50.0 mL of the filtrate add 0.5 mL of [sulfuric acid R](#). Evaporate to dryness and ignite the residue to constant mass at 600 ± 50 °C. The residue weighs a maximum of 5 mg.

[Loss on drying \(2.2.32\)](#)

22.0 per cent to 27.0 per cent, determined on 0.500 g by drying in an oven at 125 °C.

ASSAY

Dissolve a quantity equivalent to 0.200 g of the dried substance in [water R](#) and dilute to 300 mL with the same solvent. Carry out the complexometric titration of calcium ([2.5.11](#)).

1 mL of [0.1 M sodium edetate](#) is equivalent to 21.82 mg of $\text{C}_6\text{H}_{10}\text{CaO}_6$.

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